Remarks

Claims

Claims 1-53 are pending in the present applications. Claims 7-12, 16, 20, 24 and 28-53 are withdrawn from consideration. Claims 1-6, 13-15, 17-19, 21-23 and 25-27 have been rejected.

Claims 1-5, 13-15, 17-19, 21-23 and 25-27 have been amended, and new claims 54-62 are submitted herewith.

Rejections under 35 U.S.C. §112, second paragraph

On page 2, the Office rejects claims 1-3, 13-15, 17-19, 21-23 and 25-27 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

In particular, the Office considers the term "a protein according to SEQ ID No. 4" in claims 1, 13, 17, 21 and 25 indefinite as it is allegedly unclear whether the term "according to" means exact correspondence. The Office suggests to replace "according to" with "comprising" to obviate this rejection.

In response, Applicants have amended the claims according to the Office's suggestion. Applicants note that the claims encompass amino acid sequences that include additional amino acids before and at the end of SEQ ID No. 4.

Also on page 2, the Office rejects claims 2-3, 14-15, 18-19, 22-23 and 26-27 as indefinite in their recitation of "a nucleic acid sequence." In particular, the Office takes the position that it is unclear whether, e.g., a subsequence of SEQ ID NO:1 or the complete SEQ ID NO:1 is intended to be covered. The Office suggests to replace "a" before nucleic acid sequence with "the."

In response, Applicants have amended the claims according to the Office's suggestion.

Rejections under 35 U.S.C. §112, first paragraph

Written Description

On pages 3-4, the Office rejects claims 4-6 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, the Office alleges that the claims are broadly drawn to any nucleic acid from any source that hybridizes under conditions of moderate stringency to either SEQ ID No: 1, 2 or 3 or any portion thereof, wherein "portion" is defined in the specification as at least 8 contiguous nucleotides, or any DNA from any source which has at least 70% identity thereto, or any DNA from any source encoding a protein having at least 80% homology to SEQ ID NO:4, wherein said encoded protein "participates in meiocyte formation."

The Office alleges that the specification only provides guidance for the isolation and characterization of a single gene encoding a single protein which participates in meiocyte formation, wherein said gene is the SPOROCYTELESS gene from *Arabidopsis thaliana* which comprises SEQ ID NO:1, with the coding sequence of nucleotides 81-1024, and which encodes SEQ ID NO:4. The Office further argues that no guidance is presented for the identification or isolation of any protein with 80% homology to SEQ ID NO:4 which would retain the ability to participate in meiocyte formation, or for any of a multitude of nucleic acid sequence variants or portions from a multitude of sources which would encode such a protein.

Furthermore, the Office states that since SEQ ID NO:3 corresponds to the Ds transposon which was used to isolate the plant gene via transposon tagging, rather than corresponding to the isolated plant gene itself, a multitude of sequences which hybridize to SEQ ID NO:3 would not encode a plant protein which "participates in meiocyte formation," and that said multitude of sequences have not been described in any way by the instant specification.

The Office relies in its rejection on University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The Office argues, among others, that in this decision, the court held that to adequately describe a claimed genus, "patent owner **must** describe a representative number of the species of the claimed genus" [emphasis added].

The Office concludes that given the claim breadth and lack of guidance provided, the specification fails to provide an adequate written description of the of the genus as broadly claimed.

Applicants have amended claim 4 to omit the recitation of SEQ ID NO:3 (Ds transposon). Applicants have also amended claim 4 to extend the definition of "portions thereof" to 40 consecutive nucleotides, as supported on page 9, line 2 of the specification. Applicants believe that these amendments address many of the Office's concerns. As a result of these amendments, the genus embraced by the amended claims covers a more defined number of species.

Applicants also note that, while the disclosure provides the specifically disclosed sequences as part of its working examples, it actually provides guidance for the isolation and characterization of all sequences according to the presently claimed invention. For specific page references, please see the discussion under the heading "Enablement" below.

Applicants further note that to satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. The written description requirement can be met through disclosure of a representative number of species or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. MPEP §2163 II. A. 3. (a)(ii); Regents of the University of California v. Eli Lilly, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Thus, a representative number of species is one way, though only one of many ways, to provide an adequate written description. Also, there is a strong presumption that an adequate written description of the claimed invention is present in the application as filed. MPEP §2163 I.A.; In re Wertheim, 191 USPQ 90, 97 (CCPA 1976).

The rejected claims define the invention by both structure and functional characteristics. Claims 4 and 5 as amended define the invention with two structural identifiers, namely percentile of hybridization and sequence identity, and a functional characteristic, participation in meiocyte formation in a plant.

Applicants respectfully submit that hybridization coupled with a functional statement has been sanctioned by the PTO (see Example 9, Revised Interim Written Description Guidelines) as an acceptable way to comply with the written description requirement.

With regard to the rejection of claim 6, Applicants submit that the invention is claimed in terms of one structural identifier, namely, homology to a known amino acid sequence, and a functional characteristic, namely, involvement in meiocyte formation in a plant, and thus also meets the standards set by Eli Lilly.

In view of the above, Applicants respectfully requests withdrawal of the written description rejections.

Enablement

On pages 5-7, the Office rejects claims 4-6 under 35 U.S.C. §112, first paragraph, for lack of enablement.

The Office acknowledges that the specification enables claims to a nucleic acid from *Arabidopsis thaliana* which comprises the SPL gene comprising SEQ ID NO:1 or which encodes SEQ ID NO:4 including variants of SEQ ID NO:1 which encode SEQ ID NO:4 resulting from the degeneracy of the genic code. However, the Office contends that the specification only provides guidance for the isolation and characterization of a single homeotic gene. The Office also contends that the isolation and evaluation of homeotic genes involved in the formation of reproductive organs in plants is unpredictable. The Office relies in particular on the disclosure of Spielman et al.

The Office concludes that, given the claim breadth, the lack of knowledge about meiocyte -involved genes, and the allegedly exceptional nature of *Arabidopsis*, it would require undue experimentation to identify and evaluate the array of genes covered by claims 4-6. The Office also notes the references to the Ds transposon in claims 4 and 5.

Applicants submit that the enablement standard is an objective one. Thus, as long as there is sufficient guidance provided in the specification how to make and use the invention, the requirement is met. Also, it is respectfully submitted that there is a presumption that an allegation of enablement of the claimed invention in the specification is correct. In re Marzocchi, 169 USPQ 367, 370 (CCPA 1971). In the present application, see, e.g., last full paragraph on page 34 of the specification for how to identify and isolate SPL genes in other plant species according to standard methods.

Prominent factors that are to be considered in a determination as to whether there is sufficient evidence to support that a disclosure satisfies the enablement requirement and whether any necessary experimentation is undue include: the breadth of the claim; the state of the prior art; the level of predictability in the art; the amount of direction provided by the inventor; the existence of working examples. MPEP §2164.01 citing In re Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The breadth of the claim

As discussed above under "written description," Applicants have amended claim 4 to omit the recitation of SEQ ID NO:3 (Ds transposon). Applicants have also amended claim 4 to extend the definition of "portions thereof" to 40 consecutive nucleotides, as supported on page 9, line 2, of the specification. Applicants believe that these amendments address many of the Office's concerns.

The state of the prior art & the level of predictability in the art

The Office cites Spielman et al. to support its allegation that isolating and evaluating homeotic genes in the formation of reproductive organs in plants is unpredictable. Applicants note that Spielman et al. do in fact state that little progress has been made to uncover how meiosis is initiated and regulated in plants despite decades of research. However, Spielman et al. also indicate that the very method the inventors have used and disclosed in detail, namely the analysis of mutants, has between 1988 and 1997 led to progress in this area (see paragraph bridging pages 2645-2646). In fact, in the first paragraph on page 2655 referred to by the Office, Spielman et al. report a success rate of 5-50% for their experiments.

Accordingly, Applicants respectfully submit that Spielman et al. does not support the Office's contention that the relevant art is unpredictable. At best, Spielman et al. does demonstrate that some experimentation might be required to make the claimed invention. However, there is no indication that this experimentation would be undue.

The amount of direction provided by the inventor & the existence of working examples

Applicants submit that the specification provides sufficient guidance and working examples as to how to make and use the invention as claimed in claims 4-6. The disclosure includes, apart from general guidance on pages 34 and 35, working examples that lead the person skilled in the art through the steps required to isolate the SPL gene (see Examples 1-4). In addition, the availability of the isolated SPL gene will greatly facilitate the isolation of the nucleic acids claimed in claims 4-6 (see second full paragraph on page 5 of the disclosure). Accordingly, Applicants submit, even if the art involved were, as the Office alleges, unpredictable, which Applicants deny, the specification provides sufficient direction and guidance of how to make and use the invention.

Applicants respectfully submit that the above supports that any experimentation needed in context of the invention claimed in claims 4-6 will not be undue.

On pages 7-8, the Office rejects claims 13-15, 17-19, 21-23 and 25-27 under 35 U.S.C. §112, first paragraph, for lack of enablement. In particular, the Office contends that the specification does not provide any guidance for the transformation of any plant species with SEQ ID NO:1, its coding region, or any nucleic acid which encodes the corresponding protein, wherein male- or female- sterile plants are obtained.

The standards for enablement have been discussed above.

The state of the prior art & the level of predictability in the art

The Office cites Matsuoka et al. and Schiefthaler at al. to support its argument that plant transformation with homeotic genes is unpredictable.

Matsuoka discusses a homeobox sequence from rice. Transformation of Matsuoka's sequence into rice results in abnormal morphologies of the transgenic rice plant. This leads the author to conclude that the product of the isolated homeobox sequence is related to the plant development process. Thus, Applicants respectfully submit, the abnormal morphologies reported by Matsuoka et al. are no more than an indication that the respective homeobox gene is in fact involved in a plant's developmental process. Matsuoka et al. do not attach any significance to the abnormal morphologies that go beyond this indication.

Accordingly, Applicants submit that the fact that ectopic transformation with a homeobox sequence, the product of which is potentially only a part of an array of proteins involved in the developmental processes it helps to control (see first paragraph on page 1040 of Matsuoka), does not provide any evidence of unpredictability of the relevant art.

Schiefthaler, the second reference cited by the Office, does transform a plant with what the Office states to be the claimed gene. The transformation is successful and achieves the desired results. Schiefthaler et al. do not do more than note that transcription patterns in other floral organs such as petals occur without visible phenotype and provide some potential interpretations of these observations. This, by itself, does not provide compelling evidence that the relevant art is unpredictable.

The amount of direction provided by the inventor & the existence of working examples

Applicants submit that the present invention provides sufficient guidance and working examples as to how to make and use the claimed invention. The present disclosure includes working example 7 that teaches the transformation of Landsberg plants by vacuum infiltration. The specification also provides general guidance as to how to make the claimed invention, e.g., on pages 19-21. Accordingly, even if the art involved were, as the Office alleges and which Applicants deny, unpredictable, the

specification provides sufficient direction and guidance of how to make the invention.

Rejections under 35 U.S.C §102(a) and 102(b)

On page 9 of the Action, the Office rejects claims 1 to 6 under 35 U.S.C. §102(a) as anticipated by Reichert et al. and claims 2 to 5 under 35 U.S.C. §102(b) as anticipated by Rousley at al. The Office has provided sequence search results showing Reichert's sequence (Accession No. 081836, submitted June, 1998) and Rousley's sequence (Accession No. B98482, submitted 1997).

Reichert et al. teach a hypothetical amino acid sequence substantially corresponding to SEQ ID NO:4 which is said to be derived from a nucleic acid. The sequence appears to have been first **published** by the EMBL/GenBank/DDBJ databases in **November of 1998**. Rousley et al. teach a nucleic acid sequence of seemingly unknown functionality showing some sequence alignment with the SEQ ID NO:1. The Rousley et al. sequence appears to have been first **published** on **March 31, 1998**. (see attachments to Office Action).

Applicants submit herewith a declaration under 37 CFR §1.131 by Dr. Wei-Cai Yang, one of the inventors of the present application. The declaration establishes, among others, that the inventors had sequenced the genomic sequences which correspond to SEQ ID NO:2 on or prior to July 13, 1997 and analyzed it within a fortnight. The declaration also establishes that some time on or prior to September 17, 1997 the complete SEQ ID NO:1 was obtained and the peptide sequence (SEQ ID NO:4) was deducted therefrom. Applicants note that in Exhibit 3, SEQ ID NO:1 begins at base 353 and ends at base 552.

Applicants respectfully submit that the declaration shows completion of the invention prior to the publication date of the Reichert et al. reference (Accession No. 081836) and the Rousley et al. reference (Accession No. B98482) as cited by the

Office.

In addition, with respect to the rejections of claims 2 and 3 in view of Rousley et al., Applicants note that claims 2 and 3 require that the claimed sequences encode a protein according to SEQ ID NO:4. The Sequence Search attached to the Office Action indicates that a substantial part of the center of the presently claimed sequences is not accounted for by Rousley's sequence. Thus, Applicants respectfully submit that Rousley's sequence will not encode a protein according to SEQ ID NO:4.

With respect to the rejections of claims 4 and 5 in view of Rousley et al., Applicants note that these claims as amended require that the claimed sequences participate in meiocyte formation in a plant. Applicants further note that there is no disclosure in Rousley et al. that the amino acid encoded by Rousley's sequence participates in meiocyte formation in a plant.

On pages 10 and 11, the Office rejects claims 4-5 under 35 U.S.C. §102(b) as being anticipated by Weigel et al and Pnueli et al.

In response, Applicants have amended claims 4 and 5 to increase the number of nucleotides that are encompassed by the term "portions thereof" to at least 40 nucleotides. Upon request, Applicants will provide printouts of the appropriate sequence alignments.

Applicants respectfully submit that these amendments overcome the rejections in view of Weigel et al and Pnueli et al.

In view of the foregoing amendments and discussions, Applicant's respectfully submit that the pending claims are in condition for allowance.

In the event that this paper is not accompanied by the full fee required for its consideration, the Commissioner is authorized to charge any insufficient or missing fees to RFEM's deposit account No. 02-2135. The Commissioner is also authorized to deposit any overpayment to the same account. A duplicate copy for the financial branch is enclosed.

RESPECTFULLY SUBMITTED,			
NAME AND REG. NUMBER	Joyce von Natzmer, Reg. No. 48,120		
SIGNATURE	Joyce v. Natzmer	DATE	7/11/03
Address	Rothwell, Figg, Ernst & Manbeck 1425 K Street, N.W., Suite 800		
City	Washington	*State*	D.C.
Country	U.S.A.	*Telephone*	202-783-6040